Federal Fraud and Abuse Laws:
A Summary
For Community Access Program Grantees

Prepared for the Health Resources and Services Administration

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I. EXECUTIVE SUMMARY

CAP grantees, like all providers participating in federal healthcare programs, have the responsibility of complying with the various federal fraud and abuse statutes. This technical advisory paper addresses the three major laws of which CAP Grantees must be cognizant.

The Federal Anti-Kickback Statute: This statute seeks to prevent fraudulent or abusive business arrangements that may compromise independent clinical judgment or raise costs for federal health care programs. The anti-kickback law prohibits any person from paying or receiving remuneration (something of value) in return for referrals for patient services (or the purchase or lease of goods or services) payable by a federal health care program. There are exceptions to this law, which were created to protect truly legitimate practices that do not give rise to these potentially fraudulent business associations. These "safe harbors" protect arrangements such as personal services and management contracts, referral services agreements, and space and equipment rental agreements so long as all of the pre-requisites are met, thereby assuring the legitimacy of the business venture. Failure to fall within one of these "safe harbors" does not make the arrangement illegal per se; however, CAP consortia should be prepared to respond to potential review by the Office of the Inspector General ("OIG"). If grantees want greater certainty for an arrangement that falls outside a safe harbor, they can apply for an advisory opinion from the OIG.

The Federal Physician Self-Referral Laws: The "Stark Law," as this statute is known as, prohibits physicians from making referrals for certain designated services to entities with whom the physician has a financial relationship. For the purposes of this statute, physicians, group practices, partnerships, and corporations are all treated as "entities," thereby broadening the scope of this law from its initial appearance. There are statutory and regulatory exceptions to this broad prohibition that provide protection to those arrangements which meet certain requirements. For example, exceptions exist for fair market value agreements, compliance training, and preventative screening agreements. However, unlike the anti-kickback statute, if an arrangement fails to comply with the Stark Law and does not meet an exception, it is *per se* illegal.

Federal False Claims Laws: Both the Social Security Act and the Federal False Claims Act prohibit filing false reimbursement claims with the federal health care programs. Criminal penalties include up to $25,000 in fines and/or five years imprisonment, and the act authorizes civil fines of treble damages, plus $5,000 or $10,000 *per false claim submitted.* In addition, the statute contains a whistleblower provision which allows a private citizen to bring suit on behalf of the government for violations of the law and receive between 15-25% of the government's ultimate recovery. This "whistleblower provision" creates no additional legal obligations for federal grant recipients; however, it creates a strong incentive for insiders to report illicit behavior.

As CAP grantees negotiate arrangements, they need to ensure that the business relationships comply with these requirements and that systems are in place to ensure that claims submitted to federal programs are accurate. Further, grantees need to review state fraud and abuse law to ensure that they do not impose additional requirements.

II. INTRODUCTION

As CAP Grantees consider creating and restructuring relationships among themselves and with third parties, they need to be mindful of the federal fraud and abuse statutes. This technical advisory paper addresses the three principal fraud and abuse laws that could affect CAP Grant recipients. The Federal Anti-kickback Statute is designed primarily to prevent one entity from offering or receiving remuneration in exchange for referrals to or from another entity or purchase or lease of goods and services paid for by federal health care programs. The Federal Prohibition on Physicians Self-referrals ("Stark II") creates limits on the ability of the physician to refer patients for designated health services if the physician has a financial relationship with that entity. The Federal False Claims Act provides potentially severe sanctions for the "knowing" submission of False Claims to a federal government program. In the sections below, the paper provides information regarding the requirements established under these laws and the exceptions or safe harbors available to providers.

III. FEDERAL ANTI-KICKBACK STATUTE

The Federal Anti-kickback Statute seeks to prevent fraudulent and abusive business arrangements, which might cause conflicts of interest in patient care decisions, create unfair advantages for certain health care providers in a competitive market place, or result in higher costs for the federal government's health care program. The statute prohibits:

- Knowingly or willfully
- Soliciting, receiving, offering to pay, or paying
- Any remuneration (something of value), whether directly or indirectly, overtly or covertly, in cash or in kind,
- In return for referring or inducing a referral for
- Patient services OR purchases or leases of equipment, goods, or services
- Any of which is payable in whole or in part by a federal health care program.[1]

Penalties include $25,000 fines, five-year prison sentences, and/or exclusion from federal health care programs. In addition, violating the anti-kickback statute could be

[1] 42 U.S.C. §1320a-7b (1994).

grounds for a civil False Claims Act suit, which authorizes recoveries of up to treble damages and $5,000 or $10,000 per claim.

The statutory language is very broad, and court decisions interpreting the law have not narrowed its scope. In fact, courts have found violations of the anti-kickback statute when this knowing or willful intent to induce referrals was ***only one reason*** amongst several (otherwise permissible) motivations behind an arrangement. Similarly, the intent to induce referrals need not be the primary purpose behind an agreement for the anti-kickback statute to be triggered,[2] and paying fair-market value for services rendered may not necessarily "rescue" an arrangement tainted by this unlawful intent. In other words, any business arrangement can potentially violate the anti-kickback statute if a single motivation behind the agreement is the intent to induce referrals for services or purchases/lease of equipment.

There are regulations that create exceptions to this otherwise broad prohibition. These "safe harbors" are narrowly drafted to protect truly legitimate practices that pose no threat of harm to the Medicare or Medicaid programs. To be protected under a specific safe harbor rule, the arrangement must meet each and every requirement of that rule; practices requiring the protection of two safe harbors must meet the requirements of both regulations.

It is important to note that failing to meet the exact requirements of a safe harbor regulation does not mean that an arrangement violates the anti-kickback statute *per se*. Rather, the Office of the Inspector General ("OIG") of the U.S. Department of Health and Human Services ("HHS") reserves the right to review non-qualifying arrangements on a case-by-case basis and decide whether prosecution is warranted. Given the narrow breadth of the safe harbor provisions, many legitimate relationships may appear to be in technical violation of the anti-kickback statute and therefore subject to case-by-case review for compliance. For arrangements outside a safe harbor, CAP consortia should be prepared to respond to potential review by the OIG at a later date.

A. Safe Harbor Regulations

The following are general descriptions of some of the safe harbor rules that are most likely to be relevant to the CAP program. The appendix includes the specific requirements for each safe harbor rule described.

1. Personal Services and Management Contracts Safe Harbor:

The Personal Services and Management Contracts rule excludes from the anti-kickback statute contracts for personal services as long as the service agreement meets the threshold requirements and the written agreement contains certain provisions. For example, there must be a written contract, signed by all parties, which specifies all of the services that will be provided. The minimum term of the service agreement must be one

[2] United States v. Kats, 871 F.2d 105 (9th Cir. 1989)

year. Compensation paid over the term of the agreement must be set in advance, cannot exceed fair market value of the service, and cannot take into account the volume or value of business generated between the parties.

2. Referral Services Agreements Safe Harbor:

The referral services agreements safe harbor insulates agreements where a general practitioner or specialist agrees to refer particular patients to a specialist or sub-specialist with the expectation that the patient will be referred back when the patient has reached a particular level of recovery. Certain criteria must be met before an arrangement will qualify for the safe harbor. For example, both referrals must be proper in that the referral to the specialist is for services the referring doctor cannot provide, and the same patient is referred back at an agreed time or circumstance that is clinically appropriate. Payment cannot be based on the volume or value of the referrals or business otherwise generated based on the relationship between the two entities, and the only permissible remuneration in this setting is the payments received from patients or third-party payers (including Medicare or Medicaid).

3. Obstetrical Malpractice Insurance Subsidies Safe Harbor:

An arrangement in which a hospital or other entity pays for the malpractice insurance premiums for a provider of obstetrical services in a primary care Health Professional Shortage Area ("HPSA") [3] can be excluded from the anti-kickback statute under the Obstetrical Malpractice Insurance Subsidies Safe Harbor. The practitioner must ensure that seventy-five percent of the obstetrical patients treated under the insurance policy either reside in a HPSA or Medically Underserved Area ("MUA") or are a part of a Medically Underserved Population ("MUP").[4] Moreover, the written agreement between the parties must set out the terms for providing the premiums as well as the amount of the premiums.

4. Space and Equipment Rental Safe Harbors:

Rental agreements for either space or equipment can be protected under the respective safe harbors as long as the requirements for the safe harbor are met. For example, the term of the rental agreement must be for at least one year, and the agreement must be written and signed by all parties.

There are other safe harbors addressing a variety of topics. Prior to entering into transactions, particularly with other providers, the CAP entity shall seek legal advice as

[3] HPSA is a designation given by the Secretary of HHS to identify geographic areas or populations groups with a shortage of primary health care services. The HPSA designation is a prerequisite to apply for National Health Service Corps assistance and can include primary medical care, mental health, and/or dental care.

[4] MUAs and MUPs are areas and populations designated by the Secretary of HHS as having a shortage of available health care services based on such factors as the ratio of the local population to primary care physicians, infant mortality rates, poverty rates, or the percentage of the local population over age 65.

to whether the transaction might run afoul of the anti-kickback law or possibly be "safe harbored."

B. OIG Advisory Opinions

If an arrangement does not fall within a safe harbor and a CAP consortium wants to be absolutely certain that an arrangement is permissible, the consortium or a provider can apply for an OIG advisory opinion. The OIG will consider requests for advisory opinions from individuals or entities regarding an existing arrangement or one that the requestor(s) intends to undertake. In general, OIG Advisory Opinions are binding only on the OIG and the requesting party; however many opinions are made available to the public for guidance. There are both procedural and substantive constraints placed upon requests for advisory opinions. The appendix contains the OIG's Preliminary Checklist For Advisory Opinion Requests which provides a detailed list of requirements that must be met in order to request these opinions. The most salient concepts are set forth below.

1. Substantive Requirements

The OIG will accept requests for advisory opinions only on certain topics. Requests regarding the application of the law to a specific set of facts relating to existing or intended arrangements will be considered as long as the requesting party is related to the entity. However, requests concerning general interpretations, hypothetical situations, or third parties will not be accepted nor will the OIG accept requests regarding the same or substantially similar action that is under investigation by HHS or another government agency. The OIG has created a list of preliminary questions interested parties should review before submitting requests for an advisory opinion. Note that in many instances, parties to a transaction will go through with an arrangement pending an advisory opinion being issued, but they must be prepared to unwind the deal quickly if the opinion outcome is negative.

2. Procedural Requirements

Before the OIG will consider advisory opinion requests, certain procedural requirements must be met. For example, the requesting party or parties (who, again, must be a party or parties to the arrangement) must submit a letter and two copies which lists the names and addresses of the requestor and all other parties involved in the arrangement. The letter must contain a statement of the statute governing the question and a complete and specific description of the arrangement for which the request is made. This description should contain all relevant information with a bearing on the arrangement including background information, detailed statements of all collateral and oral understandings, the operative documents for existing arrangements, and for proposed endeavors, copies of the operative documents or their proposed description.[5] Every request must contain a certification signed by the requesting party or parties, as well as a check for $250, which will cover the initial review. Moreover, the requesting party (or

[5] For greater detail on the advisory opinion process, go to http://www.oig.hhs.gov/.

parties) is responsible for covering the costs incurred by the OIG in issuing the advisory opinion should the OIG accept the request.

Upon receipt of a request, OIG has ten days to formally accept or decline a request or notify the requesting party or parties if additional information is necessary to complete the processing of the request. Should the OIG accept the request, an advisory opinion should be issued within sixty days. Realistically, however, these opinions may take six months or more to obtain. Again, these advisory opinions are only binding on the OIG and the requesting party (or parties). However, advisory opinions are made available to the public, though names and certain information will be redacted to protect the parties, thereby providing valuable guidance concerning the OIG's enforcement considerations regarding a particular type of transaction.

3. Evolving Trends

The OIG regularly posts redacted copies of issued advisory opinions,[6] and a review of these opinions reveals an encouraging trend: arrangements which offer a positive benefit to communities and/or medically under-served populations are more likely to receive the OIG's stamp of approval for otherwise questionable arrangements.

In 1999, the OIG issued fourteen advisory opinions. Five opinions specifically acknowledged the significant benefit bestowed upon communities by arrangements which did fall within an anti-kickback safe harbor but would not be prosecuted by the OIG. Similarly, in 2000, the OIG issued eleven advisory opinions, and three of these opinions relied upon "community benefit" as one reason why the OIG would not take action against parties to a specific arrangement (a trend which has continued into the first quarter of 2001). [7]

This is not to say that arrangements that violate the anti-kickback statute can be saved from prosecution if they confer a benefit upon a medically under-served population. However, given the community outreach goals of the CAP programs, in many instances, grantees could be good candidates for favorable opinions.

C. Internal Communications

The anti-kickback statute creates a crime of intent. The fact that one of the purposes behind an arrangement may be to garner illicit referrals (or purchases or leases

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[6] These opinions can be found at www.oig.hhs.gov/advopn/index.htm.

[7] Note that a "community benefit" alone has not been a sufficient justification in any advisory opinion for OIG approval. The proposals also have needed to demonstrate that there is a minimal risk of abuse of Federal health care programs (i.e., does not present a high risk of overutilization of services or increased costs to the programs) and have generally included certain safeguards to protect against prohibited activities.

of goods and services) can taint the entire transaction. Consequently, CAP grantees must be mindful as to how they communicate both internally and externally regarding what they are trying to accomplish in creating CAP networks.

More specifically, the Health Resources and Services Administration has provided federal funding to enable a consortium of providers to come together to rationalize health care delivery to indigent and under-served individuals in one way or another. It is not providing funds so that providers can reward each other for making referrals or steering purchases/leases of goods and services. Executives and managers planning for implementation need to ensure that their communications regarding strategies and implementation focus exclusively on the legitimate purposes behind the grant funding. For instance, one arrangement may be perfectly permissible under the anti-kickback statute if its purpose is to provide more coordinated care to indigent patients. On the other hand, the same arrangement can become a felony if internal staff communication indicates that one purpose behind the deal is to reward (or induce) one provider for sending its patients to another.

Consequently, at the start of the CAP planning and implementation process, it is worthwhile to talk very explicitly about what is and is not allowed with respect to the use of grant funds. Given that people tend to be particularly careless with what they say in emails, voicemails or internal conversations, staff should be warned not to say anything or write anything that they would not want to see on the front page of a newspaper. From time to time, it may be worthwhile to provide refresher education on the restrictions imposed by the anti-kickback statute and to explain where people with questions regarding the statute restrictions can turn for answers.

IV. FEDERAL PHYSICIAN SELF-REFERRAL LAWS

In 1990, Congress acknowledged the concern that a physician may over-utilize referrals for Medicare or Medicaid services if that physician is in a position to personally benefit from the referral. In response, legislation was passed to regulate physician referrals to entities with which the physician or an immediate family member has a direct or indirect financial relationship. Named after Congressman Fortney "Pete" Stark of California, the "Stark Law" initially related only to clinical laboratories.[8] "Stark II", effective January 1, 1995, is the governing prohibition of self-referrals for a variety of designated services payable by Medicare and Medicaid. Corresponding final regulations were issued in January 2001 and will become effective on January 4, 2002.

At the date of this paper, the only specific guidance available on the “Stark” law is the statute itself, the Stark I regulations, the Stark II proposed regulations, and the Stark II “Phase I” final regulations issued in January 2001. These Phase I regulations apply only to Medicare. A second set of regulations that are being referred to as “Phase II” are currently being drafted and will address other topics, including Medicaid and certain

[8] This initial prohibition was passed as part of the Omnibus Budget Reconciliation Act of 1989 and became effective on January 1, 1992.

exceptions to the self-referral prohibitions. Phase II regulations will potentially affect CAP grant recipients, but the specifics are not yet known. Thus, CAP grantee recipients need to monitor regulatory developments in this area.

A. The Statutory Prohibition

The Stark II Law states that if a physician has a "financial relationship" with an entity, then the physician may not make a referral to the entity for "designated health services" for which payment may be made under Medicare or Medicaid.[9] Moreover, the entity may not present a claim to Medicare or Medicaid if the claim is based on a referral that violates this prohibition. No wrongful intent or culpable conduct is required to violate the Stark Law, but knowledge of the prohibited relationship is necessary to be prosecuted.

The list of "designated health services" includes:

- Clinical laboratory,
- Physical and occupational therapy,
- Radiology and other diagnostic imaging services,
- Radiation therapy,
- Parenteral and enteral nutrition,
- Outpatient prescription drugs,
- Durable medical equipment and supplies,
- Prosthetics, orthotics and prosthetic devices,
- Home health services and supplies, and
- Inpatient and outpatient services.[10]

The primary remedy is non-payment or recovery of payments made. However, penalties can include fines of up to $15,000 per claim and exclusion from Medicare or Medicaid. In addition, if wrongful intent is found, then the individual or entity can be subject to criminal charges and civil penalties under the federal false claims laws.

A Stark Law analysis breaks down into three essential questions: (1) does the relationship between the doctor and entity constitute a prohibited "financial relationship;" (2) has the doctor made or will the doctor make referrals for any of the "designated services;" and (3) are there any applicable exceptions.

For the purposes of the Stark Law, physicians include health care entities, as well as health care providers organized as group practices, partnerships, or corporations. Thus, the first question, whether the relationship between the doctor and referred entity constitutes a prohibited "financial relationship," is actually broader in scope than it may

[9] 42 U.S.C. § 1395nn (1994).

[10] Please see the appendix for a complete description of the prohibition and the services which it covers.

appear at first glance. A financial relationship includes an ownership or investment interest in an entity or a "compensation arrangement" between an entity and the referring physician or a member of his or her family.

The second question - whether the doctor has or will make referrals for any of the designated health services - breaks down into one simple concept: so long as a physician does not make referrals to entities with which he or she has a financial relationship, then no problem exists.

B. Stark II Exceptions

Regarding the third question, there are a number of statutory and regulatory exceptions to the ownership and compensation arrangement prohibition. The following are some examples of available exceptions:

- Rental of office space or equipment,
- Bona fide employment arrangements,
- Fair market value compensation,
- Indirect compensation arrangements,
- Preventative screening,
- Non-monetary compensation arrangements,
- Compliance training, and
- Personal services arrangements.

Every exception contains specific requirements, all of which must be met before a particular arrangement qualifies for the exception (much like the “safe harbors” in federal anti-kickback law). As an example, the Stark II Personal Services Exception applies to arrangements that meet each of the following criteria:

- The arrangement is set out in writing, signed by all parties, and specifies the services covered in the arrangement;

- The arrangement applies to all of the services to be referred by the physician to the entity;

- The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement;

- The term of the arrangement is for at least one year;

- The compensation to be paid over the duration of the arrangement is established in advance, does not exceed fair market value, and . . . does not account for the volume or value of any referrals or other business generated between the parties; and

- The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law.[11]

1. Fair Market Value Compensation Exception

The fair market value compensation exception protects arrangements that benefit both physicians and related entities but do not pose a risk of program abuse. Certain requirements must be met, including setting compensation in advance, ensuring that the compensation is consistent with fair market value, and making certain the compensation does not take into account the value or volume of referrals generated for the business by the referring physician.

2. Preventative Screening Test Exception

Referrals for preventative screening tests, immunizations, and vaccines are protected from prosecution under the Stark II Law so long as the criteria for the exception are met. For example, the tests must be within recommended frequency limits, reimbursed by Medicare based on a fee schedule, and the arrangement cannot violate the anti-kickback statute.

3. Non-Monetary Compensation Exception

The non-monetary compensation exception essentially carves out of the prohibition a niche for gifts or benefits provided to a referring physician. To comply with the exception and avoid triggering the Stark II law, the gift or benefit cannot be cash or cash equivalent, nor may it be determined so as to take into account the volume or value of referrals generated by the referring physician. The physician cannot receive more than $300 worth of gifts or benefits in a given year, nor can the physician or his practice solicit the benefit. And, as always, the gift or benefit must comply with the anti-kickback statute.

4. Compliance Training Exception

The compliance training exception protects training provided by a hospital to a referring physician who practices in the same community. The exception requires that such training must either cover the basic elements of a compliance program or the specific rules of a federal health care program. The compliance training exception appears to be very narrow in that it protects compliance training activities but does not appear to protect other components of compliance programs supported by the OIG such as physician assistance or creating self-audit policies. Nonetheless this exception may be particularly useful to CAP grantees that intend to provide physician training, as part of their services.

[11] The space rental and equipment lease exceptions to Stark II impose similar standards.

The specific requirements for each of the above-mentioned exceptions are stated in Appendix C.

Finally, though the Stark II and anti-kickback statutes have striking similarities, the two statutes differ in that the Stark II statute has fewer gray areas. More specifically, under Stark II, if there is a financial relationship between an entity and a physician and the physician refers patients to the entity for designated services, then the arrangement must fall within one of the statutorily defined exceptions or it is *per se* illegal. By comparison, the failure of an arrangement to fall within an anti-kickback statute safe harbor does not mean the arrangement is prohibited. Rather, the relationships are examined on a case-by-case basis. Thus, the Stark physician self-referral statutes usually impose more clear limitations on business transactions than the anti-kickback statute.

Again, this summary relates to the Stark Law and Phase I of the implementing regulations. Phase II of the regulations are currently being drafted, and once effective, these regulations are likely to affect CAP grantees.

C. Advisory Opinion Process

As is the case with the anti-kickback statute, there is a regulatory structure for requesting an advisory opinion under the Stark II statute. However, the Health Care Financing Administration has indicated that it will not issue any further advisory opinions until the Phase II regulations under the Stark law are finalized. Consequently, this paper does not cover the Stark advisory opinion process. For further updates on advisory opinions in this area, as well as for the opportunity to review the only two opinions ever issued, go to www.hcfa.gov/regs/aop/default.html.

V. FEDERAL FALSE CLAIMS LAWS

The Social Security Act and federal False Claims Act prohibit filing false reimbursement claims to federal health care programs, including Medicare and Medicaid.

A. The Social Security Act

Under the Social Security Act, an individual or entity can be subject to criminal penalties of up to $25,000 in fines and/or imprisoned for up to five years for

- knowingly and willfully
- making a false statement or representation of material fact regarding an application for benefits or payment OR failing to report any sums received to which the individual or entity is not entitled with the intent of fraudulently keeping these sums
- under a federal health care program.

Additional civil liability and penalties may be imposed if HHS determines that the individual or entity knew or should have known that the claim was false or fraudulent. Monetary penalties can be assessed for as much as $10,000 for each claim that is falsely or fraudulently submitted.

B. The False Claims Act

The False Claims Act ("FCA") was drafted to protect the Federal government from false claims in every arena, including but not limited to federal health care programs. The FCA prohibits any individual or entity from knowingly presenting a materially false or fraudulent claim to the government for reimbursement. The term "knowingly" has been interpreted by federal courts to mean that the person submitting the claim (1) has actual knowledge that the claim contains false information; (2) deliberately ignores information regarding the truth or falsity of the claim; or (3) deliberately acts in reckless disregard of the truth or falsity of the information. However, no proof of specific intent to defraud the government is required for a party to be liable under the False Claims Act.[12]

C. Whistleblower Provisions of the Federal False Claims Act

The FCA contains provisions that allow a private citizen to bring a suit on behalf of the government for violations of the False Claims Act. Those so called "*qui tam*" actions, or "whistleblower suits" allow an individual to bring a suit based on previously undisclosed information, and potentially receive anywhere between 15% and 25% of the government's ultimate recovery. While the whistleblower provisions create no new legal obligations for a federal grant recipient and CAP providers, they do provide powerful incentives for insiders or competitors to report illicit behavior. Disgruntled employees have been the most frequent source of these lawsuits. Given the powerful financial incentives for an individual to report False Claim Act violations (which authorize treble damages, plus $5,000 or $10,000 per claim), grant recipients and providers need to understand that violations of the law are likely to be detected and reported.

VI. STATE LAWS

The foregoing summaries all relate to federal laws regulating fraud and abuse in federal health care programs. However, it is important that all CAP consortia recognize that every state has its own set of laws and regulations, which may affect the structure of a particular arrangement. Similarly, states have their own false claims acts, which CAP individuals and entities will be subject to in addition to the federal laws. Therefore, CAP entities are strongly encouraged to seek legal advice regarding both federal and state laws that will affect their organizations.

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[12] United States v. Pediatric Serv. of Am., Inc., 2001 WL 435799 (W.D.N.C. 2001) at 11-12.

APPENDIX A

FEDERAL ANTI-KICKBACK STATUTORY SAFE HARBORS

Personal Services Safe Harbor

The Personal Services and Management Contracts Safe Harbor protects those contracts which:

(1) Are in writing and signed by all parties;

(2) Covers all services to be provided and the specifics of each service;

(3) If the services are not to be provided on a full time basis, the contract must specifically describe the scheduled interval of the services provided, the length of each service interval, and the exact charge for each interval;[13]

(4) The term of all agreements (full and part-time) must be at minimum one year long;

(5) The total compensation for the term of the agreement must be established in advance and cannot exceed fair market value for the provided services. Moreover, compensation cannot account for the value or volume of referrals generated;

(6) The services provided pursuant to the agreement cannot involve counseling or promotion of activities which violate state or federal laws;

(7) And the combined services provided cannot exceed what is reasonably necessary to accomplish the business purpose of the services.

[13] For example, if the services are to be provided for twelve weeks in each calendar year, the service contract must specify that services will be provided during the first full week of each calendar month, from 9am through 5pm, Monday through Friday, and for a rate of X number of dollars for each week of service.

Referral Services Safe Harbor

The following criteria must be met before a particular arrangement may qualify for the referral services safe harbor:

(1) The referring entity does not exclude participants who otherwise qualify to receive referrals;

(2) The payment made to the referring entity equals the cost of operating the referral service and is not based upon volume or value of referrals or other business otherwise generated by either party for the other;

(3) The referring service does not impose requirements on the manner in which the provider treats the referred person other than requiring the provider to charge the same rate as non-referred persons;

(4) The referring service makes the following disclosures to persons seeking referrals to providers:

(i) The way the referring service chooses the providers it refers persons to;

(ii) Whether the provider has paid a fee to receive referrals;

(iii) The manner in which the referring service selects the provider for the individual being referred;

(iv) The nature of the relationship between the referring service and the group of participants to whom it could make referrals;

(v) Any restrictions which would exclude an individual or entity from continuing as a participant.

Obstetrical Malpractice Insurance Subsidies Safe Harbor

To qualify for safe harbor protection, the obstetrical malpractice arrangement must meet the following seven requirements:

(1) the subsidy payment must be made pursuant to a written agreement that specifies the terms under which the payments are to be made;

(2) the provider must certify that for each year of the agreement, there is a reasonable basis for believing that at least 75% of the obstetrical patients treated will reside in a HPSA or MUA, or be part of a MUP;

(3) there can be no requirement that the practitioner make referrals to the entity providing the subsidy or generate business for such other entity in exchange for the subsidy;

(4) the practitioner cannot be restricted from referring patients, generating business, or obtaining staff privileges with another hospital;

(5) the amount of the subsidy cannot be related to either the value or volume of any referrals or other business generated between the practitioner and the entity providing the subsidy that may be paid by the Medicare or Medicaid program;

(6) the practitioner may not discriminate against any beneficiary of a federally-funded health care program;

(7) the subsidy must be for *bona fide* obstetrical malpractice coverage only; in the case of practitioners who do not engage in a full-time obstetrical practice in a primary care HPSA, the costs must be allocated to the non-obstetrical practice and/or to the non-HPSA portion of the practice.

Space and Equipment Rental Safe Harbors

Though separate and distinct safe harbors, the space and equipment rental safe harbors share the same pre-requisites for protection:

(1) the lease agreement is written and signed by all parties;

(2) the lease specifies the equipment or premises to be leased, the term of the lease, and it covers the entire agreement;

(3) if the rental agreement is not for full time use of the equipment or premises, the agreement shall specify exactly the schedule of use, the length of each interval, and the payment for each interval;

(4) the term of agreement is a minimum of one year;

(5) the aggregate rental charge is set in advance, is consistent with the fair market value for the premises or equipment, and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under a federal health care program;

(6) the aggregate premises or equipment rented does not exceed what is reasonably necessary to accomplish the commercially reasonable business purpose of the rental.

APPENDIX B

PRELIMINARY CHECKLIST FOR ADVISORY OPINION REQUESTS[14]

Updated July 1999, this checklist reflects the OIG final regulations published in the Federal Register on July 16, 1998 (63 FR 38311). This version of the checklist is not substantially different from the previous versions set forth. The checklist is for informational purposes only, and should not be a substitute for reading the regulations on issuance of OIG advisory opinions.

A. Technical Requirements

1. The requestor is a party to the arrangement. (42 CFR 1008.11) ____

2. The request is for an existing arrangement or one which the requestor in good faith plans to undertake. (42 CFR 1008.15(a)) ____

3. The requestor has included:

   a. A non-refundable check or money order for $250, payable to the Treasury of the United States. (42 CFR 1008.31(b) and 1008.36(b)(6)) ____

   b. A request for a written estimate of the cost involved in processing the advisory opinion. (Optional) (42 CFR 1008.31(d)(2))

   c. A designated triggering dollar amount. (Optional) (42 CFR 1008.31(d)(3)) ____

   d. An original and two copies. (Optional) (42 CFR 1008.36(a)) ____

   e. The name and addresses of the requestor and all other actual and potential parties to the extent known to the requestor. (42 CFR 1008.36(b)(1)) ____

   f. The name, title, address, and daytime telephone number of a contact person. (42 CFR 1008.36(b)(2)) ____

   g. Each requesting party's Taxpayer Identification Number. (42 CFR 1008.36(b)(8)) _____

   h. Full and complete information as to the identity of each entity owned or controlled by the individual, and of each person with an ownership or control interest in the entity. (42 CFR 1008.37) ____

[14] The OIG reserves the right to modify this checklist at any time or to request additional information not specified on this checklist.

i. If applicable, a statement that some or all of the information or documents provided are trade secrets or are privileged or confidential commercial or financial information and are not subject to disclosure under the Freedom of Information Act. (42 CFR 1008.36(b)(4)(v)) ____

B. Describing the Issues and the Arrangement

The request includes:

1. A declaration of the subject category or categories for which the opinion is requested. (42 CFR 1008.36(b)(3)) ____

2. A complete and specific description of all relevant information bearing on the arrangement and on the circumstances of the conduct. (42 CFR 1008.36(b)(4)) ____

3. All relevant background information. (42 CFR 1008.36(b)(4)(i)) ____

4. Complete copies of all operative documents, if applicable, or narrative descriptions of those documents. (42 CFR 1008.36(b)(4)) ____

5. Detailed statements of all collateral or oral understandings (if any). (42 CFR 1008.36(b)(4)(iii)) ____

C. Certifications

1. The request includes a signed certification that all of the information provided is true and correct and constitutes a complete description of the facts regarding which an advisory opinion is sought. (42 CFR 1008.38(a)) ____

2. The certification is signed by –

   a. The requestor if the requestor is an individual. (42 CFR 1008.38(c)(1)) ____

   b. The CEO or comparable officer if the requestor is a corporation.

      (42 CFR 1008.38(c)(2)) ____

   c. The managing partner if the requestor is a partnership.

      (42 CFR 1008.38(c)(3)) ____

3. If the request is for a proposed arrangement, it contains a signed certification that the arrangement is one that the requestor in good faith plans to undertake.

   (42 CFR 1008.38(b)) _____

APPENDIX C

STARK II PHYSICIAN SELF-REFERRAL PROHIBITION EXCEPTIONS

Preventative Screening Tests, Immunizations, and Vaccines

Preventive screening tests, immunizations, and vaccines may be excepted if the following conditions are met:

(1) The preventive screening tests, immunizations, and vaccines are covered by Medicare and identified by the CPT and HCPCS codes;[15]

(2) The preventive screening tests, immunizations, and vaccines are subject to HCFA-mandated frequency limits;

(3) They are reimbursed by Medicare based on a fee schedule;

(4) The arrangement for the provision of these services does not violate the Federal anti-kickback statute, section 1128B(b) of the Act; and

(5) Billing and claims submission for the preventive screening tests, immunizations, and vaccines complies with all federal and state laws and regulations.

Non-Monetary Compensation Exception

Compensation from an entity in the form of items or services (not including cash or cash equivalents) that does not exceed an aggregate of $300 per year may be excepted from the Stark II Law if all of the following conditions are satisfied:

(1) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician;

(2) The compensation may not be solicited by the physician or the physician's practice (including employees and staff members); and

(3) The compensation arrangement does not violate the federal anti-kickback statute.

[15] The HCPCS and CPT codes can be found on the web site of the Health Care Financing Administration ("HCFA") and in annual updates published in the Federal Register.

Fair Market Value Compensation Exception

Compensation resulting from an arrangement between an entity and a physician (or an immediate family member) or any group of physicians (regardless of whether the group meets the definition of a group practice set forth in Sec. 411.351) for the provision of items or services by the physician or group practice to the entity may be excluded from the Stark Law prohibition if the arrangement meets the following conditions:

(1) The arrangement must be in writing, signed by the parties, and covers only identifiable items or services, all of which are specified in the agreement;

(2) The agreement specifies the duration of the arrangement, which can be for any period of time and can contain a termination clause provided the parties have only one arrangement in effect at any given time for the same items or services;

(3) The duration of the agreement may be for less than one year and may be renewed any number of times as long as the terms of the arrangement and compensation for the same items or services do not change;

(4) The compensation must be arranged in advance, be consistent with fair market value, and cannot be determined in a manner that takes into account the volume or value of any referrals or any other business generated by the referring position;

(5) The compensation must be specified in the written agreement;

(6) The arrangement must be commercially reasonable in terms of both the nature and scope of the transaction, and the arrangement must further the legitimate business purposes of all the parties;

(7) The arrangement must be in compliance with the federal anti-kickback statute (it must not violate the statute or it must meet a safe harbor or have been approved by the OIG under a favorable advisory opinion issued specifically for the arrangement); and

(8) The services to be performed under the agreement may not involve the counseling or promotion of a business arrangement or other activity that violates state or federal law.

Compliance Training Exception

Compliance training provided by a hospital to a physician (or an immediate family member) who practices in the hospital's local community or service area does not violate the Stark II Law so long as the training is held in the local community or service area. For the purposes of this exception, "compliance training" means training regarding the basic elements of a compliance program – such as establishing policies and procedures, training of staff, internal monitoring, reporting – or specific training regarding the requirements of federal health care programs, including billing, coding, reasonable and necessary services, documentation, unlawful referral arrangements.

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